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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,375	12/08/2003	Philip J. Barr	368292001700	4368
25226	7590	10/20/2004	EXAMINER	
MORRISON & FOERSTER LLP			KIM, JENNIFER M	
755 PAGE MILL RD			ART UNIT	
PALO ALTO, CA 94304-1018			PAPER NUMBER	
			1617	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,375

Applicant(s)

BARR ET AL.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/14/2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-12 are presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Shapiro (U.S. Patent No. 6,489,308B1) evidenced by Grote et al. (U.S. Patent No. 6,670,327B1).

Shapiro teaches a novel method of treating and preventing disease such as chronic otitis media (with effusion) comprising administration of alpha one-antitrypsin. (abstract, column 13, line 45). Shapiro teaches troleandomycin and 7-nitroindazole (antibiotics) can be administered with alpha one-antitrypsin for the treatment. (column 13, lines 17-20). Shapiro teaches the therapeutic agents comprising alpha one-antitrypsin can be administered to mammals, including humans, as well as mammals such as non-human primates, dogs, cats, horses, cows, pigs, guinea pigs and rodents.

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(column 17, lines 15-20). Shapiro teaches the agents can be formulated as a liquid medicine or in powder form. (column 17, lines 30-38, column 19, line 14, lines 60-65).

Grote et al. report that the term "otitis media" refers to a spectrum of diseases which fluid (effusion) is present in the middle ear space and chronic otitis media is when middle ear effusion has been present for a least three month. (column 1, lines 15-30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 7-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro (U.S. Patent No. 6,489,308B1) as applied to claims 1-4, 6 and 10 above, and further in view of Grote et al. (U.S. Patent No. 6,670,327B1).

Shapiro as applied as before.

Shapiro does not teach specific conditions such as a perforated tympanic membrane, chronic suppurative otitis media and treating chronic suppurative otitis media together with antibiotics or steroids.

Grote et al. teach the use of corticosteroids or antibiotics for the treatment of otitis media is common. (column 2, lines 2, lines 34-45). Grote et al. teach that conditions such as tympanic membrane perforation, cholesteatoma and chronic

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suppurative otitis media are complications associated with otitis media. (column 6, lines 20-35).

It would have been obvious to one of ordinary skill in the art to modify the teaching of Shapiro to employ alpha one-antitrypsin for the treatment of chronic otitis media in human suffering from a perforated tympanic membrane, chronic suppurative otitis media and chronic suppurative otitis media because alpha one-antitrypsin is useful for the treatment of chronic otitis media and because the conditions such as tympanic membrane perforation, cholesteatoma and chronic suppurative otitis media are complications associated with otitis media as taught by Grote et al. One would have been motivated to employ alpha one-antitrypsin for the treatment of a conditions associated with otitis media such as tympanic membrane perforation, cholesteatoma and chronic suppurative otitis media in order achieve an expected benefit of alpha one-antitrypsin in treatment of chronic otitis media in general as taught by Shapiro. Further, to employ antibiotics or steroid in combination with alpha one-antitrypsin is obvious since each of the active agents are known to have same utility for treatment of otitis media as taught by Grote et al. One would have been motivated to combine antibiotics or steroids in combination with alpha one-antitrypsin for the treatment of otitis media condition in order to achieve at least an additive effect for the treatment of otitis media associated conditions.

For these reasons the claimed subject matter deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

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None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
October 15, 2004